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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): COLE, Laurence A.
SERIAL NO.: 10/616,323
FILED: July 9, 2003
FOR: Hyperglycosylated hCG (Invasive Trophoblast Antigen) In
Differential Diagnosis of Malignant or Invasive Trophoblast
Disease
GROUP ART UNIT: 1642
EXAMINER: Peter J. Reddig

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22331-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56(a), applicant encloses herewith a copy of Form PTO-1449 listing documents relevant to the background of the invention described and claimed in the above-identified application. For the convenience of the Examiner, copies of the listed documents are enclosed.

Applicant respectfully requests that the Examiner consider the enclosed references in determining the patentability of the claimed invention. Applicant also requests that the Examiner return a copy of enclosed Form PTO-1449 with initials or other marks indicating that the references have been so considered. If any fee is due, please charge/credit deposit account no. 04-0838.

Respectfully submitted,

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Dated: 5-12-06



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: "Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on May 12, 2006.

Harold Hull

Harold Hull



INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Att'y Ref: N12-003US	Serial No: 10/616,323
	Applicant: Laurence A. COLE	
	Filing Date: July 9, 2003	Art Unit: 1642

United States Patent Documents						
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date

Foreign Patent Documents							
Examiner Initial	Publication Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No

Examiner Initial	Other Documents (by Title, Author Date, Pertinent Pages, Etc.)
	Cole LA. Phantom hCG and phantom choriocarcinoma. Gynecol Oncol 1998; 71:325-329
	Rotmensch S, Cole LA. False diagnosis and needless therapy of presumed malignant disease in women with false-positive human chorionic gonadotropin concentrations. Lancet 2000; 355:712-715
	Cole LA, Shahabi S, Butler S, Mitchell H, Newlands E, Behrman HR, Verrill HL. Utility of commonly used commercial hCG immunoassays in the diagnosis and management of trophoblastic diseases. Clin Chem 2001; 47:308-315

Examiner:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.	

	Cole LA, Butler SA. False positive or phantom hCG result: a serious problem. Clin Lab Intl 2001; 25:9-14.
	Cole LA, Butler SA. Detection of hCG in Trophoblastic Disease: The USA hCG Reference Service experience. J Reprod Med 2002; 47:433-444
	Butler SA, Cole LA. The Use of heterophilic antibody blocking agent (HBT) in reducing false positive hCG results. Clin Chem 2001; 47:1332-1333
	Butler SA, Cole LA. Falsely elevated hCG leading to unnecessary therapy (letter). Obstet Gynecol 99:516-517, 2002
	Cole LA, Shahabi S, Oz UA, Bahado-Singh RO, Mahoney MI. Hyperglycosylated hCG (invasive trophoblast antigen) immunoassay: a new basis for gestational down syndrome screening. Clin Chem 1999; 45:2109-2119
	Suzuki T, Goto S, Nawa A, Kurauchi O, Saito M, Tomoda Y. Identification of the pregnancy responsible for gestational trophoblastic disease by DNA analysis. Obstet Gynecol 1993;82, 629-34
	Kohorn El. Persistent low-level 'real' human chorionic gonadotropin: a clinical challenge and a therapeutic dilemma. Gynecol Oncol 2002; 85:315-320.
	Newlands -ES. Presentation and management of persistent gestational trophoblastic disease and gestational trophoblastic tumors in the UK. In: Hancock BW, Newland ES, Berkowitz RS, editors. Gestational Trophoblastic Disease. London: Chapman and Hall; 1997. p. 143 - 156
	Berkowitz RS, Goldstein DP. Presentation and management of molar pregnancy. In: Hancock BW, Newland ES, Berkowitz RS, editors. Gestational Trophoblastic Disease. London: Chapman and Hall; 1997. p. 127-142
	O'Connor JF, Elish N, Kakuma T, Schlatterer J, Kovalevskaya G. Differential urinary gonadotrophin profiles in early pregnancy and early pregnancy loss. Prenat Diagn 1998; 18:1232-1240
	Elliott MM, Kardana A, Lustbader JW, Cole LA. Carbohydrate and peptide structure of the α - and (3-subunits of human chorionic gonadotropin from normal and aberrant pregnancy and choriocarcinoma. Endocrine 7, 15-32, 1997

Examiner:

Date Considered:

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